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10/798,941	03/10/2004	Ruud Philip Antoon Maria Segers	I 1997.267 US D2	6641

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/798,941

Applicant(s)

SEGERs ET AL

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Amendment Entry***

1. The amendment filed June 13, 2005 has been entered. The examiner acknowledges the amendment to the specification. Claims 1-19 have been cancelled. Claim 20 has been newly added. Claim 20 is under consideration in this office action.

### **Withdrawal of Rejections**

2. The following rejections have been withdrawn in view of applicants' amendments:

- a) The written description rejection of claims 7-9 rejected under 35 U.S.C. 112, first paragraph;
- b) The rejection of claims 7-9 under 35 U.S.C. 112, second paragraph;
- c) The rejection of claims 7-9 under 35 U.S.C. 101; and
- d) The rejection of claims 7-9 under 35 U.S.C. 102(b) as being anticipated by Frey.

### ***New grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claim is drawn to a nucleotide sequence harbouring the promoter controlling the expression of the *A. pleuropneumoniae* RTX-operon type IV (Apx IV) gene, characterized in that said nucleotide sequence comprises the DNA fragment from position 594 to 641 of SEQ ID NO:5.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.' *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ('[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'). Thus, an applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, not that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.' *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or

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disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Furthermore, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.*, the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . ."). *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The specification refers to SEQ ID NO:5, however the specification provides no guidance as to what other nucleotides may be encompassed by the claimed nucleotide sequence. Moreover, the claim recites open language and therefore includes a wide variety and unlimited number of additional nucleotides. Yet there is no disclosure of how many of these other nucleotides may be present. The claim fails to limit the number of additional nucleotides within the sequence yet recites that the nucleotide sequence which must only comprise nucleotides 594 to 641 of SEQ ID NO:5. Therefore all sequences having the same nucleotides as those with positions 594 to 641 of SEQ ID NO:5 are being claimed, along with all other possible combinations of nucleotides. There is no

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specific limitation for what additional nucleotides may be included. However the unlimited additions have not been taught and/or enabled by the specification.

Thus, the nucleotide sequence harbouring the promoter controlling the expression of the *A. pleuropneumoniae* RTX-operon type IV (Apx IV) gene, characterized in that said nucleotide sequence comprises the DNA fragment from position 594 to 641 of SEQ ID NO:5 fails to meet the written description provision of 35 UCS 112, first paragraph. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, make clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Thus, the structure of the entire nucleotide sequence is not defined. Even though claim 20 recites that the sequence must comprise at least positions 594 to 641 of SEQ ID NO:5, the claim does not limit the number of other nucleotides that may be included in the sequence. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for production.

Thus a skilled artisan cannot envision all the contemplated nucleotide sequence and therefore conception cannot be achieved until reduction to practice has occurred. It is noted however that applicants' are not required to disclose every species encompassed by a genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the

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variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli*, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618. In view of the specification failure to disclose the identity or adequately describe a nucleotide sequence harbouring the promoter controlling the expression of the *A. pleuropneumoniae* RTX-operon type IV (Apx IV) gene, characterized in that said nucleotide sequence comprises the DNA fragment from position 594 to 641 of SEQ ID NO:5, a skilled artisan would be required to de novo locate, identify and characterize the claimed sequence. Therefore the full breadth of the claim fails to meet the written description provision of 35 USC 112, first paragraph.

4. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Acronyms like *A. pleuropneumoniae* RTX-operon must be spelled out when used for the first time in a chain of claims. Therefore *Actinobacillus pleuropneumoniae Repeat In Toxin (A. pleuropneumoniae RTX-operon)* would be appropriate to overcome the rejection.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 20 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 20 is drawn to a sequence that naturally occurs. Moreover, the open claim language allows the sequence to comprise more than just nucleotides 594 to 614 of EQ ID NO:5, the claimed sequence has no limit and can therefore be the entire genome.

Furthermore, Dreyfus et al., (2004) teach that ApxIV is expressed by all serotypes of *Actinobacillus pleuropneumoniae* (*A. pleuropneumoniae*) after infection of pigs (page 228). Thus, any pig with an *A. pleuropneumoniae* infection inherently comprises a nucleotide sequence harboring the promoter controlling the expression of the *apxIV* gene. Moreover, positions 594 to 641 of SEQ ID NO:5 are the same nucleotides as those from the wild-type strain, thus, the nucleotide sequence naturally occurs. For example, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. See M.P.E.P. 2105.

It is noted that applicants' recitation of "isolated" does not obviate the rejection because there is no limit on the nucleotides encompassed within the entire claimed sequence and because the instantly claimed nucleotide sequence occurs naturally and is not entitled to patent protection. The claimed sequence has no markedly different characteristics than any found in nature, therefore, the claims are drawn to non-statutory subject matter and not entitled to patent protection.

### **Conclusion**

6. No claims allowed.



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7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines   
August 17, 2005

  
WITA MINNIFIELD  
PRIMARY EXAMINER  
8/18/05